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SCIENTIFIC OPINION

Safety assessment of the process brtCOMBIPET used to recycle post-consumer PET into food contact materials

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The EFSA Panel on Food Contact Materials (FCM) assessed the safety of the recycling process brtCOMBIPET (EU register number RECYC338). The input is washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are dried (step 6), melted in an extruder (step 7) and pelletised, dried and crystallised (step 8). The pellets are then preheated, further crystallised, then decontaminated in a solid-state polymerisation (SSP) reactor (step 9) and cooled down. Having examined the challenge tests provided, the Panel concluded that the extrusion, the preheating and the SSP are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance are the temperature and the pressure for step 7 (extrusion) as well as the temperature, residence time and gas flow rate for step 9 (preheating and SSP). It was demonstrated that this recycling process ensures that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.0481 or 0.0962 μg/kg food, depending on the molar mass of the contaminant substance. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern, when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature or below, with or without hot-fill. Articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

KEYWORDS

brtCOMBIPET, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment, Zhejiang BORETECH Environmental Engineering Co. LTD

CONTENTS

1 | INTRODUCTION

1.1 | Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Articles 17 and 18 of Commission Regulation (EU) 2022/1616[1] on recycled plastic materials intended to come into contact with foods. More specifically, according to Article 18 of Commission Regulation (EU) 2022/1616 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food, to evaluate the microbiological safety of these materials and articles and to deliver a scientific opinion on the recycling process examined.

According to this procedure, the process developers submit applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation. In this case, EFSA received an application from the Dutch competent authority, for evaluating the recycling process brtCOMBIPET, European Union (EU) register No RECYC338. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2023-00419. The dossier was submitted by Zhejiang BORETECH Environmental Engineering Co., LTD, No.888, Jiuliting Avenue, Caoqiao Street, Pinghu, Zhejiang, China (see 'Documentation provided to EFSA').

1.2 | Terms of Reference

The Dutch competent authority requested the safety evaluation of the recycling process brtCOMBIPET, in compliance with Article 17 of Commission Regulation (EU) 2022/1616. The recycling process uses the recycling technology number 1 of the list of suitable recycling technologies of Table 1 of Annex 1 of Commission Regulation (EU) 2022/1616.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant submitted a confidential and a non-confidential version of a dossier, following EFSA's 'Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food' (EFSA CEP Panel, 2024) and EFSA's 'Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food' (EFSA, 2024).

Additional information was received from the applicant during the assessment process, in response to requests from EFSA sent on 10 July 2024 and on 12 June 2025 (see 'Documentation provided to EFSA'). Following the request by the Working Group, a technical hearing was held with the applicant on 10 June 2025.

In accordance with Art. 38 of the Regulation (EC) No 178/2002[2] and taking into account the protection of confidential information and the personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[3] the non-confidential version of the dossier has been published on Open.EFSA.[4]

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations[4], EFSA carried out a public consultation on the non-confidential version of the application from 16 October to 06 November 2024, for which no comments were received.

The following information on the recycling process was provided by the applicant and used for the evaluation (EFSA, 2024; EFSA CEP Panel, 2024):

- Recycling process,
- Determination of the decontamination efficiency of the recycling process,
- Table of operating parameters,
- Self-evaluation of the recycling process.

[1]Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Commission Regulation (EC) No 282/2008. OJ L 243, 20.9.2022, p. 3–46.

[2]Commission Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[3]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[4]The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2023-13431.

2.2 | Methodologies

The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (EFSA CEP Panel, 2024).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific guidance developed by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel, 2024). The principle of the evaluation is to apply the decontamination efficiency of a recycling process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 μg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible, considering different dietary exposure scenarios (EFSA CEP Panel, 2024). If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered of safety concern for the defined conditions of use (EFSA CEP Panel, 2024).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment, considering the relevant guidance from the EFSA Scientific Committee (EFSA, 2009).

3 | ASSESSMENT

3.1 | General information[5]

According to the applicant, the recycling process brtCOMBIPET is intended to recycle food grade PET containers. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs, including drinking water. The final articles are intended for long-term storage at room temperature or below, with or without hot-fill. The final articles are not intended to be used in microwave or conventional ovens.

3.2 | Description of the process

3.2.1 | General description[6]

The recycling process brtCOMBIPET produces recycled PET pellets from PET materials originating from post-consumer collection systems.[7]

Input

- In steps 1–5, the post-consumer PET is processed into washed and dried flakes.

Decontamination and production of recycled PET material

The decontamination process comprises the four steps below.

- In step 6, the flakes are dried under air flow at high temperature.
- In step 7, the flakes are extruded under vacuum.
- In step 8, the melt is converted into pellets which are then dried and crystallised.
- In step 9, the pellets are preheated, further crystallised and decontaminated in a solid-state polymerisation (SSP) reactor.

Following decontamination, the pellets are cooled down using a fluidised bed cooling system. The operating conditions of the process have been provided to EFSA.

[5]Technical dossier, section 'Intended application in contact with food'.
[6]Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.
[7]The collected plastic waste should comply with Art. 6 of Reg. (EC) 2022/1616.

3.2.2 | Characterisation of the preprocessed plastic input[8]

According to the applicant, the input material consists of washed and dried flakes obtained from PET materials, e.g. bottles, previously used for food packaging, from post-consumer collection systems. A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%, as specified in Article 7 and Table 1 of Annex I of Commission Regulation (EU) 2022/1616.

Technical specifications on the washed and dried flakes are provided, such as on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, glue, labels, polystyrene (PS), polyamide (PA), polycarbonate (PC), metals and other materials (see Appendix A).

3.3 | brtCOMBIPET process

3.3.1 | Description of the main steps[9]

The process flow diagram, as provided by the applicant, is reported in Figure 1.

The decontamination steps are:

- Drying (step 6): The flakes are continuously dried at high temperature via hot air flow in a static tumble drier for a defined residence time. The air is recycled passing through a dehumidifier.
- Extrusion (step 7): The flakes from the previous step are melted under vacuum in a twin-screw co-rotating extruder and the melt is filtered.
- Pelletisation, drying and crystallisation (step 8): The melt is solidified in an underwater pelletising system, the pellets are dried at high temperature and crystallised on a vibrating table.
- Preheating and SSP (step 9): In the preheater, the pellets are further crystallised while preheated under nitrogen flow up to the temperature of the SSP. They are further decontaminated in the SSP reactor, under defined conditions of temperature, residence time and nitrogen flow.

After the decontamination steps, the hot pellets are cooled down in a fluidised bed cooling system.

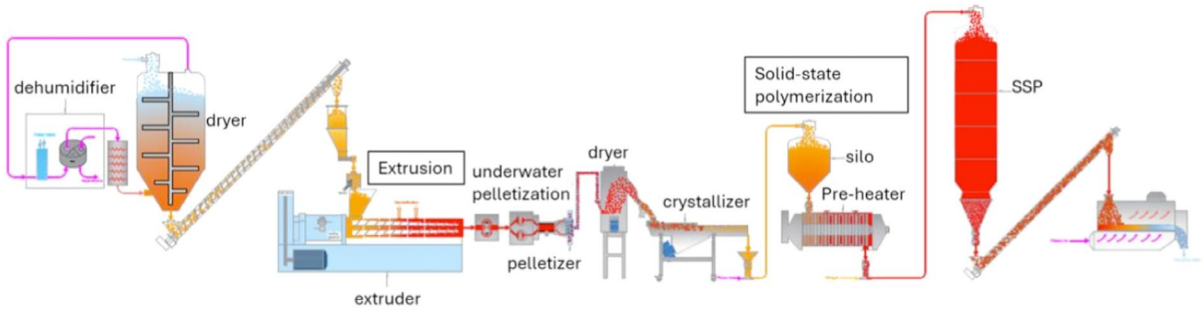

FIGURE 1 Process flow diagram of the brtCOMBIPET process (provided by the applicant).

The process is run under defined operating parameters[10] of temperature, pressure, gas flow and residence time. The critical parameters are monitored by sensors and documented. The applicant suggests periodical documentation, for instance via operation log sheets.[11]

According to the applicant, the pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, colour and pellet size. The applicant also recommends regular testing for migration and extractable substances by the recycler.[12]

[8]Technical dossier, section 'Characterisation of the input'.

[9]Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

[10]In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004, the parameters were provided to EFSA by the applicant and made available to the Member States and the European Commission (see Appendix C).

[11]Technical dossier, Sections 'Recycling Process' and 'Quality Assurance System'.

[12]Technical dossier, Section 'Characterisation of the recycled plastic'.

3.3.2 | Decontamination efficiency of the recycling process[13]

To demonstrate the decontamination efficiency of the recycling process brtCOMBIPET, two challenge tests, CT1 and CT2, performed on steps 7–8 and step 9, respectively, were submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, phenylcyclohexane, benzophenone, methyl salicylate and methyl stearate, selected as surrogates in agreement with the EFSA Scientific Guidance (EFSA CEP Panel, 2024) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2021).

Separately prepared surrogate cocktails were added to 10 masterbatches of blue-coloured PET flakes and mixed. The masterbatches of contaminated PET were then added to 10 steel drums containing 27 kg of non-contaminated green flakes. The drums were rolled and stirred and then kept at 60°C for 8 days, during which period they were rolled another six times. After the washing, the (colour-coded) contaminated flakes were recovered via a colour sorter and the concentrations of the surrogates were determined.

Six batches of contaminated flakes were dried at pilot scale (step 6). They were then subjected to extrusion, pelletisation and crystallisation in continuous mode at industrial scale (first challenge test, CT1). Samples were taken before step 7 (extrusion) and after step 8 (pelletisation, drying and crystallisation) and the concentrations were measured.

The pellets were then mixed with non-contaminated pellets, preheated and further decontaminated in the SSP reactor (step 9) at industrial scale (challenge test CT2). The contaminated (green) pellets were separated from non-contaminated (white) pellets and analysed. The Panel noted that dichloromethane was used under mild conditions to extract the samples. For this application and considering a similar extraction efficiency in the samples taken before and after the decontamination steps, the results were considered adequate for the calculation of the decontamination efficiency. Cross-contamination from the contaminated to the non-contaminated pellets was accounted for by assuming a concentration of the surrogates in the non-contaminated pellets as 10% of the concentration in the contaminated ones.

The decontamination efficiencies of steps 7–8 (extrusion and pelletisation/crystallisation, CT1) and of step 9 (preheating and SSP reactor, CT2) were calculated from the starting and final concentrations of surrogates for each challenge test. The results are summarised in Tables 1 and 2.

TABLE 1 Efficiency of the decontamination in steps 7–8 (CT1) of the brtCOMBIPET process.

Surrogates	Concentration of surrogates before step 7 (mg/kg PET)	Concentration of surrogates after step 8 (mg/kg PET)	Decontamination efficiency (%)
Chloroform	43	2.6	94.0
Toluene	58	4.9	91.6
Chlorobenzene	106	12	88.7
Methyl salicylate	90	1.4	98.4[a]
Phenylcyclohexane	109	31	71.6
Benzophenone	147	74	49.7
Methyl stearate	68	28	58.8

Abbreviation: PET, poly(ethylene terephthalate).

[a]The Panel noted that methyl salicylate may have been unstable under the extrusion conditions.

TABLE 2 Efficiency of the decontamination in step 9 (CT2) of the brtCOMBIPET process.

Surrogates	Concentration of surrogates before step 9 (mg/kg PET)	Concentration of surrogates after step 9 (mg/kg PET)	Decontamination efficiency[a] (%)
Chloroform[b]	–	–	–
Toluene	5.66	< 0.116[c]	> 91.2
Chlorobenzene	13.2	< 0.112[c]	> 96.4
Methyl salicylate[d]	2.16	< 0.112[c]	–
Phenylcyclohexane	30.8	< 0.105[c]	> 98.5
Benzophenone	68.6	< 0.224[c]	> 98.6
Methyl stearate	29	< 0.119[c]	> 98.2

Abbreviation: PET, poly(ethylene terephthalate).

[a]Recalculated by the Panel. Calculations included cross-contamination.

[b]Chloroform was not detected due to the high limit of detection (LOD) of the method and it was not further considered in the calculations.

[c]Below the limit of quantification (LOQ).

[d]Due to likely instability of methyl salicylate under the process conditions, the Panel decided not to further consider the data for the determination of the decontamination efficiency.

The combined decontamination efficiency of the process was then calculated from the decontamination efficiencies of steps 7–8 and step 9 (Table 3).

[13]Technical dossier, Section 'Determination of the decontamination efficiency of the recycling process'.

TABLE 3 Combined decontamination efficiency of the brtCOMBIPET process derived from the two individual challenge tests.

Surrogates	Decontamination efficiency (%) steps 7–8	Decontamination efficiency (%) step 9	Combined decontamination efficiency (%)
Toluene	91.6	> 91.2	> 99.3
Chlorobenzene	88.7	> 96.4	> 99.6
Phenylcyclohexane	71.6	> 98.5	> 99.6
Benzophenone	49.7	> 98.6	> 99.3
Methyl stearate	58.8	> 98.2	> 99.3

The Panel noted that the overall decontamination efficiencies of the process are expected to be higher, since additional decontamination occurs during drying (step 6).

3.4 | Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Specifications on the input material (i.e. washed and dried flakes, steps 1–5) are listed in Appendix A.

The flakes are produced from PET containers, e.g. bottles, previously used for food packaging, collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouthwash or kitchen hygiene agents. According to the applicant, the collection system and the sorting are managed in such a way that this fraction will be no more than 5% in the input stream, as recommended by the EFSA CEP Panel in its Guidance (EFSA CEP Panel, 2024).

The process is adequately described. It comprises the drying (step 6), extrusion (step 7), pelletisation, drying and crystallisation (step 8), preheating and SSP (step 9). The operating parameters of temperature, residence time, pressure and gas flow have been provided to EFSA.

For steps 7–9, the challenge tests were conducted at an industrial scale. The Panel considered that they were performed correctly according to the recommendations of the EFSA Guidance (EFSA CEP Panel, 2024). The decontamination of the material in steps 7 and 9 is critical. Consequently, the temperature and the pressure for step 7 (extrusion) as well as the temperature, residence time and gas flow rate for step 9 (SSP), as specified in Appendix C, are to be controlled to guarantee the efficiency of the decontamination.

The decontamination efficiencies obtained for each surrogate, ranging from above 99.3% to above 99.6%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}). By applying the decontamination efficiency percentage to the reference contamination level of 3 mg/kg PET, the C_{res} values shown in Table 4 were obtained.

According to the evaluation principles (EFSA CEP Panel, 2024), the dietary exposure must not exceed 0.0025 μg/kg bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that, after 1 year at 25°C, results in a migration giving rise to a dietary exposure of 0.0025 μg/kg bw per day. As the recycled PET is intended for the manufacturing of articles (e.g. bottles) to be used in direct contact with drinking water, the exposure scenario for infants has been applied for the calculation of C_{mod} (Exposure Scenario A; water could be used to prepare infant formula). A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.0481 μg/kg (= 5 × 0.00962 μg/kg) or 0.0962 μg/kg (= 10 × 0.00962 μg/kg), depending on the molar mass of a contaminant substance[14] into infant's food and has been used to calculate C_{mod} (EFSA CEP Panel, 2024). C_{res} reported in Table 4 is calculated for 100% recycled PET. The results of these calculations are shown in Table 4. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

TABLE 4 Combined decontamination efficiency from the challenge tests, residual concentrations of the surrogates (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates in PET corresponding to a modelled migration of 0.0481 μg/kg or 0.0962 μg/kg after 1 year at 25°C (C_{mod}).

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET) scenario A
Toluene	> 99.3	< 0.022	0.04
Chlorobenzene	> 99.6	< 0.012	0.05
Phenylcyclohexane	> 99.6	< 0.012	0.13
Benzophenone	> 99.3	< 0.021	0.15
Methyl stearate	> 99.3	< 0.022	0.29

Abbreviations: PET, poly(ethylene terephthalate); rPET, recycled poly(ethylene terephthalate).

[14]Correction factors of 5 and 10 are applied for contaminants with molecular masses ≤ 150 Da and > 150 Da, respectively (EFSA CEP Panel, 2024).

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that, under the given operating conditions, the recycling process brtCOMBIPET is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.0481 or 0.0962 µg/kg, depending on the molar mass of a contaminant substance into infant's food. At this level, the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce materials and articles intended for contact with all types of foodstuffs, including drinking water (exposure scenario A), and used for long-term storage at room temperature or below, with or without hot-fill.

4 | CONCLUSIONS

The Panel considered that the process brtCOMBIPET is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the extrusion (step 7) as well as preheating and SSP (step 9) are critical for the decontamination efficiency. The parameters to control the process performance are the temperature, the residence time, the gas flow and the pressure, specified in Appendix C.

The Panel concluded that the process is capable of reducing contamination of post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

(i) it is operated under conditions that are at least as severe as those applied in the challenge tests used to measure the decontamination efficiency of the process;
(ii) the input material of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and contain no more than 5% of PET from non-food consumer applications;
(iii) the recycled PET obtained from the process brtCOMBIPET is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, and used for long-term storage at room temperature or below, with or without hot-fill.

The final articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

5 | RECOMMENDATION

The Panel recommended periodic verification that the input to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and the Commission Regulation (EU) 2022/1616. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

6 | DOCUMENTATION PROVIDED TO EFSA

Dossier 'brtCOMBIPET'. March 2024. Submitted on behalf of Zhejiang BORETECH Environmental Engineering Co., LTD., China.

Additional information, March 2025. Submitted on behalf of Zhejiang BORETECH Environmental Engineering Co., LTD., China.

Additional information, September 2025. Submitted on behalf of Zhejiang BORETECH Environmental Engineering Co., LTD., China.

ABBREVIATIONS

bw	body weight
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
FCM	Panel on Food Contact Materials
PET	poly(ethylene terephthalate)
SSP	solid-state polymerisation

REQUESTOR

Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz)

QUESTION NUMBER

EFSA-Q-2023-00419

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PANEL MEMBERS

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WAIVER

In accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management, a waiver was granted to an expert of the Working Group. Pursuant to Article 21(6) of the aforementioned Decision, the concerned expert was allowed to take part in the preparation and discussion of the scientific output but was not allowed to take up the role of rapporteur within that time frame. Any competing interests are recorded in the respective minutes of the meetings of the FCM Panel Working Group on Recycling Plastics.

LEGAL NOTICE

Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by EFSA. The full output has been shared with the European Commission, EU Member States (if applicable) and the applicant. The blackening may be subject to review once the decision on the confidentiality requests is adopted by EFSA and in case it rejects some of the confidentiality requests.

REFERENCES

EFSA (European Food Safety Authority). (2009). Guidance of the scientific committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part2: General principles. *EFSA Journal*, *7*(5), 1051. https://doi.org/10.2903/j.efsa.2009.1051

EFSA (European Food Safety Authority). (2024). Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food. *EFSA Journal*, EN-8968. https://doi.org/10.2903/sp.efsa.2024.EN-8968

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids). (2024). Scientific guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food. *EFSA Journal*, *22*(7), 8879. https://doi.org/10.2903/j.efsa.2024.8879

FDA (Food and Drug Administration). (2021). Guidance for industry: Use of recycled plastics in food packaging: Chemistry considerations. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

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APPENDIX A

Specifications of the preprocessed input material* as provided by the applicant[8]

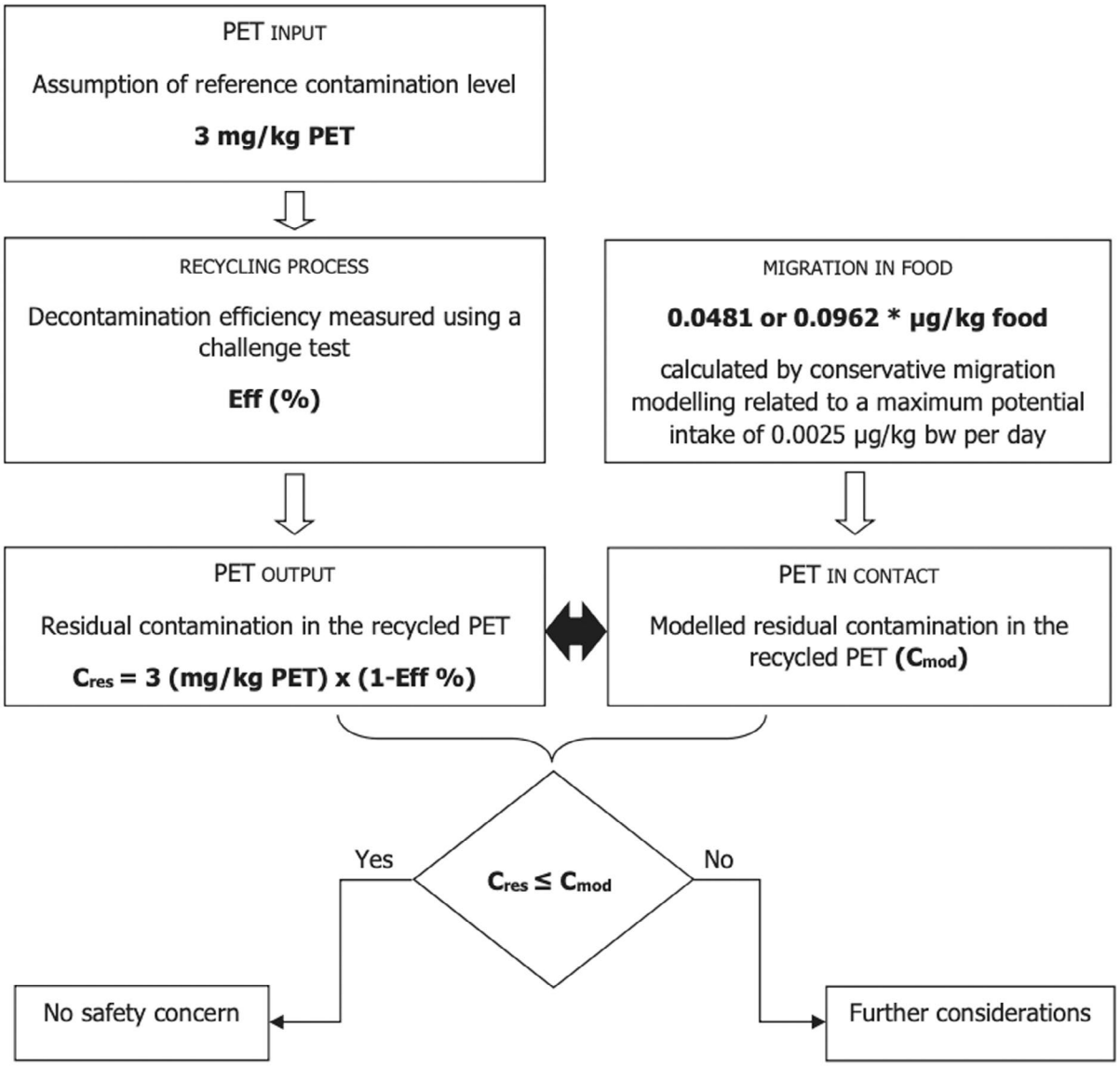
Parameter	Value
PVC	≤ 20 mg/kg
Polyolefins	≤ 30 mg/kg
Flakes with glue	≤ 300 mg/kg
Label	≤ 20 mg/kg
PS, PA and PC	≤ 100 mg/kg
Yellow PET after baking	≤ 5000 mg/kg
Light blue flake	≤ 1000 mg/kg
Yellow flake	≤ 1000 mg/kg
Coloured PET flake	≤ 300 mg/kg
Ferrous metal	≤ 10 mg/kg
Non-ferrous metal	≤ 20 mg/kg
Others (wood, rubber, textile, glass, etc.)	≤ 30 mg/kg
L-value (CIE colour space)	65
b-value (CIE colour space)	1
Moisture	≤ 2%
Bulk density	≥ 250 g/L
Average bulk density	330 g/L
Intrinsic viscosity	≥0.7 dL/g
Dimensions	8 mm
Flake size distribution	2–10 mm
Average flake thickness	0.5 mm

Abbreviations: PA: Polyamide; PC, Polycarbonate; PS, polystyrene; PVC, poly(vinyl chloride).

*Foreign plastics in the flakes can be determined by 'oven testing'.

APPENDIX B

Relationship between the key parameters for the evaluation scheme, based on the most conservative scenario A (EFSA CEP Panel, 2024)



*Depending on the molecular mass of the surrogate substance, the figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg bw per day applying the factors of 5 and 10 related to the overestimation of modelling (most conservative Scenario A).

APPENDIX C

Table of operational parameters[15]

[redacted]

Process brtCOMBIPET (RECYC338)

	Step 6				Step 7			Step 8			Step 9						
	Drying				Extrusion			Underwater pelletising and crystallisation			Preheating			SSP			
	t (min)	*P* (mbar)	Gas flow rate (m^3/h)	*T* (°C)	*t* (min)	*P* (mbar)	*T* (°C)	*t* (min)	*P* (mbar)	*T* (°C)	*t* (min)	Gas flow rate (m^3/h)	*T* (°C)	*t* (min)	*P* (mbar)	Gas flow rate (m^3/h)	*T* (°C)
Challenge tests CT1 and CT2*	180	Atmospheric	[redacted]	[redacted]	5 (including Step 8)	[redacted]	Average [redacted] (7 zones)	5 (including Step 7)	Atmospheric	Pelletisation: [redacted] Crystallisation: 140–160**	30	[redacted]	[redacted]	960	[redacted] [redacted]***	[redacted]	[redacted]
	Batch				Continuous			Continuous			Continuous			Continuous			
Process	120–180	Atmospheric	[redacted]	[redacted]	5–10 (including Step 8)	[redacted]	Average [redacted] (7 zones)	5–10 (including Step 7)	Atmospheric	Pelletisation: [redacted] Crystallisation: 140–160**	30–40	[redacted]	[redacted]	960–1080	[redacted] [redacted]***	[redacted]****	[redacted]
	Continuous			Continuous				Continuous			Continuous			Continuous			

* CT1 (steps 7–8): Report No. TUV Rheinland 89218560 001; CT2 (step 9): Report No. P40001-40148v3.** Temperature of the pellets at the crystalliser outlet. Crystallisation time is [redacted] min.*** [redacted].**** Corresponding to gas velocity of [redacted]

[15]Technical dossier, Sections 'Table of operating Parameters' and 'Recycling process'.